# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Salomol Inhaler-Salbutamol Aerosol Inhalation BP

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 100 micrograms of salbutamol.

## 3 PHARMACEUTICAL FORM

Pressurised Inhalation suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

4.1.1 Treatment and prophylaxis of bronchial asthma.
4.1.2 Treatment of bronchitis and emphysema and conditions with associated reversible airways obstruction.
4.1.3 Relief of acute dyspnoea.
4.1.4 Particularly suitable for treatment of bronchospasm in patients with co-existing heart disease or hypertension.

### 4.2 Posology and method of adminstration

*Adults:*
(i) Acute bronchospasm and intermittent episodes of asthma – one of two inhalations as a single dose.
(ii) Chronic maintenance or prophylactic therapy – two inhalations three or four times daily.
(iii) To prevent exercise induced bronchospasm – two inhalations should be taken before exertion.

*Children:*
(i) Acute bronchospasm and intermittent episodes of asthma or before exercise – one inhalation.
(ii) Routine maintenance or prophylactic therapy – one inhalation three or four times daily.

*Elderly:*
The dosage is the same as for adults.

### 4.3 Contraindications

In spite of the fact that salbutamol has been used intravenously and orally in the management of uncomplicated premature labour, salbutamol inhalation preparations should not be used for threatened abortion.

Salomol Inhaler is contra-indicated in patients with a history of hypersensitivity to any of its components.

### 4.4 Special warnings and special precautions for use

Asthmatic patients whose condition deteriorates despite salbutamol therapy, or where a previously effective dose fails to give relief for at least three hours, should seek medical advice in order that any necessary additional steps may be taken. Patients requiring long term management with salbutamol inhaler should be kept under regular surveillance.

Patients with hyperthyroidism or who are hypersusceptible should use salbutamol with caution as should those patients

suffering from diabetes mellitus, serious cardiovascular disorders or hypertension.

## 4.5 Interaction with other medicinal products and other forms of interaction

Adverse metabolic effects of high doses of salbutamol may be exacerbated by concomitant administration of high doses of corticosteroids – patients should therefore be monitored carefully when the two forms of therapy are used together.

There is evidence that no adverse interaction occurs between cardioselective beta blockers and sympathomimetic bronchodilators. Concurrent administration with beta adrenoceptor blocking agents will inhibit the bronchodilating action to an extent depending on their degree of cardioselectivity.

Caution should be exercised in the use of salbutamol with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

The effects of this product may be altered by guanethidine, reserpine methyldopa, tricyclic antidepressants and monoamine oxidase inhibitors.

## 4.6 Pregnancy and lactation

The existing data regarding the use of salbutamol during human pregnancy and lactation is insufficient to be able to assess possible harmful effects. It is therefore advised that salbutamol should be used during pregnancy or during lactation only after careful consideration by the medical practitioner.

## 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

No important side effects have been reported following salbutamol therapy. Salbutamol in high doses may cause fine tremor of skeletal muscle (particularly the hands), and peripheral vasodilation. Slight tachycardia, tenseness and headaches have also been reported after large doses, but these are less usually associated with the inhalation dosage form.

## 4.9 Overdose

Overdosage may result in skeletal muscle tremor, tachycardia, tenseness, headache and peripheral vasodilation. Preferred treatment is with cautious use of cardioselective beta-adrenoceptor blocking agents.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Salbutamol is a beta-adrenergic stimulant which has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors.

## 5.2 Pharmacokinetic properties

Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first-pass metabolism in the liver. About half is excreted in the urine as an inactive sulphate conjugate following oral administration.

## 5.3 Preclinical safety data

Not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Oleic acid
Trichlorofluoromethane
Dichlorodifluoromethane

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

36 months.

## 6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

## 6.5 Nature and contents of container

A pressurised aluminium container with metered dispensing valve. Each inhaler supplies 200 metered actuations.

## 6.6 Instructions for use and handling

Patients should be properly instructed in the correct use of the inhaler. Instructions for use are included on the Patient Information Leaflet supplied with each inhaler.

# 7 MARKETING AUTHORISATION HOLDER

Norton Waterford
Industrial Estate
Waterford
Ireland

# 8 MARKETING AUTHORISATION NUMBER

PA 436/7/1

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th April 1986
Date of last renewal: 29th April 2001

# 10 DATE OF REVISION OF THE TEXT

January 2002